
BIOLOGICS/BIOTECH
Nopras
TECHNOLOGIES, INC.
Our People Speak **Compliance**
Adroitly **Execute** Forward Thinking Strategies
And Are **Passionate** About What We Do

Nopras Technologies, Inc., is a full-service consulting company providing regulatory consulting services to the global pharmaceutical, biologics/biotechnology and medical device industries. Our staff includes experienced technical, quality, and compliance experts from industry leaders. The officers and employees of Nopras Technologies, Inc. offer a comprehensive knowledge of FDA and quality auditing procedures and practices and a unique awareness of regulatory enforcement policies and activities.

At Nopras Technologies, we believe that tremendous synergy comes from having experienced, senior level personnel from industry. Our experience also gives us a broad and detailed understanding of the complex business and compliance challenges faced by today's regulated companies.

BIOLOGICS/BIOTECHNOLOGY

Nopras TECHNOLOGIES, INC.

As the biotechnology industry matures and edges towards profitability and increased investment, many companies are entering unfamiliar territory as they deal with regulatory challenges and product launches. These are areas where Nopras Technologies can help.

Nopras Technologies personnel have extensive experience in assisting biotech companies from start-ups to large multi-nationals deal with compliance issues and product launches. We can help you cut launch time, increase yield, and ensure product safety.

Nopras Technologies services for the Biologics/Biotechnology Industry include:

- *Program Design*
- *Operational Excellence*
- *Regulatory Preparation and Submission*
- *Drug Development Support*
- *Validation Consultation*
- *Operational Support*
- *Validation Protocol Development and Execution*

PROGRAM DESIGN

We support a team structure that is focused on the goals and milestones of our clients and achieved through close communication, detailed measurement and tracking. Nopras will build flexibility into your development strategy for risk mitigation and work with you to provide seamless communications.

- Preparing gap analysis
- Designing, executing and managing integrated development plans
- Controlling cost to agreed budgets

OPERATIONAL EXCELLENCE

- Operating Costs Reduction
- Capital Expenditure Minimization
- Scaling Production to Demand
- Production Efficiency Improvement and Cycle Time Reduction
- Quality Improvement
- Process Capability and Control (PC&C)
- Six Sigma Methodologies Implementation

REGULATORY PREPARATION AND SUBMISSION

Nopras Technologies, Inc. can guide you through the complicated regulatory environment associated with product development and registration. Our team of experts have extensive regulatory experience with the US FDA, EMEA, JPAL and Health Canada. We will assist you in making sound business decisions by providing proper understanding of the potential regulatory risks before they become major regulatory roadblocks. Our team of experts have a strategic regulatory focus with attention to the challenges in the pharmaceutical, medical device and biologic/biotechnology industries. Nopras Technologies team of experts employ critical thinking to identify and resolve problems in a proactive and innovative manner.

- Regulatory submission oversight, management, preparation & maintenance (U.S., Canada, JPAL & E.U.)
- IND's, IMPD's, CTA's or individual dossier components
- Pre-BLA meeting preparation & post-meeting review
- BLA's, NDS' and MAAs in CTD format or individual dossier components
- CMC- specific: IND, IMPD, BLA, NDS, MAA, MDF/EDMF
- Preparation of regulatory submission technical sections and summaries.
- Orphan drug designation applications.
- Regulatory compliance gap analysis of product development plans and submissions
- Design/Review of preclinical pharmacology/toxicology studies
- Development of Clinical Development Plans (CDP); clinical protocol and investigator brochure development / review
- Clinical study Request for Proposal (RFP) preparation

DRUG DEVELOPMENT SUPPORT

Our consultants offer a level of experience unmatched in the industry and provide exceptional process, technical, and regulatory support:

- From small molecules and vaccines to biologics.
- Gap analysis and regulatory/scientific assessment
- Strategic advice on development
- Guidance on interactions with regulatory agencies
- Technology transfer
- Analytical methods development
- Process development and formulation development

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VALIDATION CONSULTATION

- Design Review/Qualifications
- Validation Master Planning
- 21 CFR Part 11, Electronic Records/Electronic Signature Compliance
- Validation Implementation Planning
- Validation Policies and Procedures
- Validation Training
- cGMP/Quality Systems Auditing
- Quality Systems Design, Management, Remediation
- Stability Program Design/Implementation.
- Software Supplier Audits
- Vendor Certification Process Design & Implementation

OPERATIONAL SUPPORT

- Metrology/Calibration System Development
- Standard Operating Procedures
- Preventative Maintenance Systems
- Change Control Development and Implementation

VALIDATION PROTOCOL DEVELOPMENT

Process Development and Validation

- Manufacturing Process Development and Validation
- Process Assessment and Optimization (Design of Experiments/SPC)
- Manufacturing Scale-Up
- Technology Transfer
- Technical Report Writing (Validation, etc.)
- Equipment Qualification
- Cleaning Validation

Computer Systems Validation

- Assessment and Remediation of Manufacturing, Laboratory, Medical Device, R&D Facilities & Equipment
- Computer-Controlled - Laboratory Equipment
- Database Management Systems (LIMS, ERP, MRP, MES, EMS, Doc. Management) IQ, OQ, PQ Protocols

Laboratory and Analytical Support

- Analytical Method Development and Validation
- Cleaning Validation & Analytical Testing (Verification)
- Equipment Qualification (IQ, OQ, PQ)
- Stability Program Design

Manufacturing and Manufacturing Support

- Cleaning Methods Development (Cleaning Validation)
- Sterilization Cycle Development
- Process Cycle Time Reduction
- Barrier/Isolation Systems Design
- Water Systems Validation
- Aseptic Manufacturing Systems Design
- Filling and Packaging Process Design and Validation
- Documentation Systems Assessment and Remediation

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